

Accelerated Patent Haemostasis Using a Procoagulant Disk; A Protocol Designed to Minimise the Risk of Radial Artery Occlusion Following Cardiac Catheterisation

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**ACCELERATED PATENT HAEMOSTASIS USING A PROCOAGULANT DISK; A PROTOCOL
DESIGNED TO MINIMISE THE RISK OF RADIAL ARTERY OCCLUSION FOLLOWING
CARDIAC CATHETERISATION**

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ABSTRACT:

Purpose: Radial artery occlusion following cardiac catheterisation has been linked to flow reduction and prolonged compression. We investigate whether these factors can be optimised following transradial cardiac catheterisation by using an accelerated band removal protocol facilitated by a haemostasis promoting pad, in combination with a patent haemostasis technique.

Methods: In this single centre prospective study, 389 consecutive patients undergoing TRA for coronary angiography or angioplasty were randomised to two haemostasis protocols: use of a Helix™ compression device alone (HC) or in combination with a haemostatic pad (StatSeal® disc) and an accelerated haemostasis protocol (AC). A patent haemostasis technique was employed in both study arms. The primary efficacy endpoint was the time to haemostasis and the secondary safety outcome was access site related complications: re-bleeding, haematoma and radial artery patency assessed within 24 hours using reverse Barbeau's Test (BT).

Results: Between May and Nov 2017, 191 patients were randomised to receive HC and 198 patients to AC. Compression time was significantly higher with HC as compared to AC (165.8 ± 63.1 versus 79.7 ± 41.2 minutes, $p < 0.001$). There were no significant differences in re-bleeding and RAO between groups (3.7% versus 5.6%, $p = 0.37$ and 6.3% versus 4.1%, $p = 0.33$) respectively. Incidence of haematoma was higher in AC group (4.7% versus 12.1%, $p = 0.009$).

Conclusion: A reduction in radial artery compression time can be achieved by using Statseal in association with an accelerated haemostasis protocol without increasing the risk of access site bleeding and RAO. The combination of reduced compression time combined with maintained radial flow via patent haemostasis has the potential to reduce the risk of radial occlusion after transradial catheterisation.

Key words: StatSeal, Helix compression device, Rapid deflation technique

INTRODUCTION

Use of transradial access (TRA) for cardiac catheterization procedures is increasing worldwide.^{1, 2} TRA offers significant patient benefits over transfemoral access (TFA) with fewer access site complications, improved patient comfort, reduced costs and a reduction in MACE in high risk groups.³⁻⁸ In view of this, the most recent European Society of Cardiology guidelines for management of non-ST elevation myocardial infarction (NSTEMI), recommend TRA with a class 1A indication, for invasive management of NSTEMI with PCI.⁹ However, the transradial approach is still not free from access site complications although they are low in comparison to TFA.^{6, 7, 10-12} In comparison to the femoral artery, the radial artery is small, superficial and easily compressible. This facilitates haemostasis following procedures and the use of dedicated haemostasis devices allows for almost immediate ambulation of patients, reducing post procedure nursing input.¹³⁻¹⁵

Since the introduction of TRA, there have been many advances to achieve optimal haemostasis, predominantly in an effort to minimise complications, improve patient comfort and reduce radial artery occlusion (RAO).^{16, 17} Optimising haemostasis with gentler, less prolonged and patent haemostasis has been shown to be associated with lower rates of RAO.^{10, 18}

A reduction in haemostasis time following TRA procedures potentially lessens amount of nursing input required, facilitates early discharge, reduces overall costs and has the potential to reduce radial artery occlusion rate.¹⁴ Materials to promote haemostasis have previously been used to facilitate removal of venous and dialysis lines.¹³ At our high volume radial centre we sought to evaluate a new accelerated haemostasis protocol (AHP) using our standard haemostasis compression device, the Helix™ (Figure 1A) with the addition of a haemostasis promoting disc (Figure 1B) in combination with a standard patent haemostasis technique.

METHODS

STUDY POPULATION AND RECRUITMENT

This study was a prospective, single-centre, open-label, randomized controlled trial to evaluate two haemostasis protocols following TRA coronary procedures. All patients presenting to our institution between May and November 2017 for coronary procedures irrespective of the indication were enrolled. Patients were excluded if radial access was not used, or if they were planned to be transferred to other hospitals after completion of procedure before the compression device had been removed. Patients were randomised to either an accelerated haemostasis protocol with a haemostasis promoting disc (AC group), or standard compression with Helix alone (HC group). The haemostasis promoting material is a 14mm diameter disc (StatSeal® Advanced), comprised of a hydrophilic polymer that dehydrates blood and potassium ferrate, a compound that agglomerates blood solids to create a seal without interfering with the normal haematological clotting process.

PROCEDURAL DETAILS

All procedures were carried out as standard using 5F or 6F radial sheaths (Terumo, Glidesheath Slender). All patients received heparin (at least 5000 iu for diagnostic procedures and 70–100 iu/kg for interventional procedures according to operator preference). In both groups following completion of the cardiac procedure the vascular sheath was removed in the catheterisation laboratory and compression applied with the helix device until no visible bleeding was apparent.

Following sheath removal patients were immediately ambulated and transferred to the recovery area. An oximeter was placed on the patients index finger, transient ulnar compression was applied to the patients ulnar artery, and patent haemostasis was achieved by reducing helix compression until an oximeter signal reappeared (Figure 2). In the HC group, compression time protocol was 60 minutes per 2500 iu of heparin administered. In

the AC group, we used our in-house AHP (Table 1) with the aim of achieving haemostasis within 60 minutes, irrespective of heparin dose.

Before applying the StatSeal® Advanced disc, the radial sheath is withdrawn 1-2 centimetres allowing space for the disc to be placed directly over the puncture site. This is then covered with a transparent adherent dressing before the Helix™ compression device is applied on top of disc. The sheath is then withdrawn while tightening the helix band (Figure 3). In both groups, after the allocated compression time had elapsed, pressure in the Helix™ was completely released. Following this, the Helix™ is then removed and the access site is assessed for any re-bleeding or haematoma. In the event of any re-bleeding the Helix™ was reapplied for a further 20 minutes before attempting the removal protocol again. In the AC group, the transparent dressing (with StatSeal® Advanced Disc underneath) was left in-situ and patients were advised to remove this after 24 hours.

STUDY ENDPOINTS

The primary (efficacy) endpoint was time to haemostasis defined as the total time elapsed from removal of the sheath to removal of the compression device with achievement of satisfactory haemostasis. Secondary (safety) endpoints were the incidence of (i) re-bleeding defined as any visible bleeding from the access site after initial removal of the compression device that necessitated re-application of the compression device, (ii) haematomas classified according to the Early Discharge After Transradial Stenting of Coronary Arteries (EASY) haematoma grading¹⁹ and (iii) radial artery patency checked within 24 hours following removal of the compression device using a reverse Barbeau's Test.²⁰

STATISTICAL ANALYSIS

Normality was assessed using the Shapiro-Wilk test, histograms and Q-Q plots. Normally distributed data are shown as mean \pm SD and non-parametric data as median (25-75% quartiles). Differences between the study groups were assessed using independent t-test (for continuous data) or chi-squared test (for categorical data). Statistical analysis was performed using Statistical Package for Social Sciences, SPSS v22.0 (Chicago, IL, USA). A p-value of <0.05 was considered statistically significant.

RESULTS

POPULATION CHARACTERISTICS

We enrolled 389 patients (191 randomised to HC and 198 patients to AC) between May and November 2017. Patient characteristics are listed in Table 2. Our study population had a mean age of 66, with a male: female ratio of approximately 3:1. Baseline characteristics were similar in both groups apart from a higher proportion of coronary intervention in HC group (55% vs 42.4%, $P=0.013$). Importantly, there was no significant difference in dose of heparin in the groups. Over 92% of participants in both groups had their procedure performed using a 6 Fr sheath.

TIME TO HAEMOSTASIS (PRIMARY OUTCOME)

The primary end point of time to haemostasis was significantly lower in the AC group at 79.7 ± 41.2 minutes as compared to standard compression in the HC group 165.8 ± 63.1 minutes, $p<0.001$ (figure 4)

SECONDARY SAFETY OUTCOMES

There was no significant difference in re-bleeding between the HC and AC groups (3.7% vs 5.6%, $p=0.37$) but the incidence of EASY grade I/II haematoma was more frequent in the AC group (4.7% vs. 12.1%, $p=0.009$). No patients had a haematoma larger than grade II. The rate of RAO was lower in the AC group but this difference did not reach statistical significance (6.3% vs 4.1%, $p=0.33$)

DISCUSSION

In this randomized control trial, we evaluated the efficacy of an accelerated haemostatic protocol (AHP) in conjunction with the StatSeal Advanced® haemostatic disc. Using an AHP, reduced the haemostasis time to half that of our conventional haemostasis protocol.

Moreover, this reduction was achieved without a significant increase in vascular complications such as re-bleeding and RAO. This is in-keeping with previous studies of haemostatic adjuncts following percutaneous vascular interventions.²¹⁻²³ Use of StatSeal® for TRA has been evaluated in small observational and randomised trials using various radial artery compression devices including the TR Band™ (Terumo, Japan) and Safeguard® (Merit Medical, USA). Condry et al²¹, using TR band, achieved a time to haemostasis 205+/-52 in the control group versus 77+/-20 minutes with Statseal and noted no significant increase in bleeding or reduction in post-procedural radial artery patency.¹⁵ Another observational study by De Korompay et al²² found low complication rates of haematoma (0.92%) and radial artery occlusion (0.3%), while compression time was reduced to nearly 1 hour.

In our study, the AC group had a higher incidence of haematoma but an equivalent rate of re-bleeding. This may be related to the reduced compression time not allowing for adequate haemostasis as has been observed in other studies with very low compression times^{20, 22}. Additionally the use of a 14mm round disc shaped Statseal may have reduced bleeding at the skin puncture but led to less effective haemostasis at the arterial puncture site. The small diameter of the disc may have led to uneven compression over the puncture site with most of the pressure over the skin puncture and less over the deeper, more proximal arterial puncture. The development of a rectangular shaped Statseal that allows for more even compression over a wider area may be further evaluated in the future, but was not available at the time of our study. All the haematomas observed in our participants were small (EASY grade II or less) and did not require any intervention. The rate of re-bleeding was the same in both groups and was successfully managed in all patients by reapplying compression.

The rate of RAO was the 35% higher in the HC group. Although this did not achieve statistical significance this may be due to a lack of power in our study. This observation requires further study as a reduction in RAO is an important objective. RAO has been observed in 1-30% of procedures and reduces options for repeat procedures, haemodialysis fistulae and coronary bypass grafting. Interventional operators employ a number of measures to prevent RAO, including minimising sheath size, utilising patent haemostasis, minimising access-site compression time and using adequate anticoagulation and vasodilator therapies.^{9, 24, 25} At our high volume, transradial centre, we routinely employ all

these strategies and this may account for the low overall incidence of RAO seen in our study, despite assessing RAO at a time-point when this is often more frequent.²⁶⁻²⁸

Additionally, the numerically lower rate of RAO observed in the AC group is reassuring as haematoma is often associated with higher rates of RAO due to more prolonged and occlusive pressure, often applied in response to the development of a haematoma.

In our study, we noted a significant reduction in compression time with the AHP and Statseal advance. This is not only important in terms of patient comfort and convenience, but also promotes early ambulation and increases patient satisfaction.^{20, 22}. Additionally, the decreased requirement for nursing input may contribute to the reduced costs when TRA is compared to TFA for coronary procedures²⁹. Importantly same day discharge is more likely when TRA is used, leading to markedly reduced costs compared to TFA, not only because of fewer complications but because of less utilisation of hospital resources.²⁹⁻³⁴ Patients are often still advised to be monitored for at least 4 hours post coronary intervention,^{19, 35-38} however, optimisation of post procedure care with the use of dedicated radial lounges has improved efficiency and patient satisfaction.³⁹ The use of AHPs may add further benefit in facilitating early ambulation and discharge.

Other recent studies have investigated patent haemostasis and AHPs with various types of adjunctive haemostasis devices including a chitosan-based pad⁴⁰ and QuikClot.⁴¹ They have also demonstrated decreased haemostasis times, however in these studies allergic reactions to the materials in the devices were observed. Interestingly, no such adverse immunological reactions were observed with the StatSeal Advanced® disc in our study. The StatSeal Advanced® haemostatic disc therefore appears to be a safe adjunct to achieving patent haemostasis with an AHP by allowing substantial reduction in compression time, which may lead to reduced nursing time and hospital costs.

LIMITATIONS

This trial was conducted at a single centre with considerable radial expertise and hence our findings may not be generalizable to other centres with less TRA expertise, or in centres where an alternative compression device is used. Our study is also limited by a small sample

size which limits the ability to interpret the results for study end points with low incidence such as radial artery occlusion and therefore a larger multi-centre randomised trial is required to corroborate our findings. Evaluation of radial artery patency in our study did not include ultrasound assessment, which may be more robust. Furthermore, radial artery patency is highly associated with the duration of haemostatic compression and although we report that the StatSeal Advanced® disc facilitates safe reduction of the haemostatic time, we did not include a third study arm comprising of the AHP alone. Finally, patients were not followed up to assess radial artery patency after a longer time period but it would be expected that the rate of RAO would decrease with time, as has been demonstrated in multiple studies.^{10, 16, 18, 26, 27}

CONCLUSIONS

Use of an AHP is feasible and reduces compression time. More rapid haemostasis can be achieved with use of an AHP and the StatSeal® disc without conferring significant additional complications following TRA. The Statseal Advanced® disc is a safe and effective adjunct to compression devices and may allow earlier mobilisation and reduce nursing input following TRA procedures. The effects on radial artery patency warrant further investigation in larger trials.

COMPETING INTERESTS

None.

AUTHOR CONTRIBUTIONS

JN, MAU and SAN designed the study; MAU, SAN, SM, KR, MAM and JN recruited all the patients. CSK and MR performed all statistical analyses. MAU and SAN co-drafted the manuscript. All authors provided critical input for revision of the manuscript and approved the final version of the manuscript.

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Table 1: Accelerated Haemostasis Protocol used with the StatSeal® Advanced Disc.

This applies to all patients regardless of antithrombotic therapy.

1. Prepare site by cleaning and drying the patient's wrist area.
2. Withdraw transradial sheath 3-4 cm.
3. Centre StatSeal® Advanced Disc over the dermatotomy and secure it with a transparent dressing. Apply product label next to StatSeal® Advanced Disc.
4. Apply the Helix™ band around the wrist, centring the Helix™ pressure pad directly over the arteriotomy, and tighten the band while slowly removing the sheath.
5. Observe the site for bleeding or swelling.
6. Transfer patient to recovery area.
7. Apply a pulse oximeter to the patient's thumb or index finger.
8. Perform a Barbeau test by compressing the ulnar artery.
9. Gradually loosen the Helix™ band until a Barbeau A, B or C waveform appears - document the waveform.
10. Occluded ulnar artery + A, B or C waveform = PATENT HAEMOSTASIS
11. Leave Helix™ band in place for 40 minutes. Monitor for bleeding or swelling.
12. After 40 minutes, immobilize the wrist and slowly reduce all pressure in the Helix™ band. Assess for re-bleeding.
13. In case of haematoma or re-bleeding then recompress with the Helix™ device for a further 20 minutes and observe.
14. After 20 minutes, if no further bleeding remove the Helix™ band.
15. Prepare patient for discharge. Instruct patient to avoid lifting or strenuous activity with the operative side for 24-48 hours.
16. Instruct patient to leave the StatSeal® disc dressing in place for 24 hours.

Table 2: Baseline Characteristics

Variable	HC n=191	AC n=198	P value
Age, years	65.7 ± 10.7	66.2 ± 10.8	0.62
Male	140 (73.3)	133 (67.2)	0.19
Diabetes	40 (20.9)	48 (24.2)	0.44
Height (cm)	171.0 ± 9.7	169.7 ± 9.2	0.20
Weight (Kg)	85.5 ± 17.1	82.8 ± 16.6	0.11
BMI (Kg/m ²)	29.2 ± 5.2	28.8 ± 5.5	0.45
eGFR, ml/min/1.73 m ²	75.7 ± 16.8	77.2 ± 15.6	0.39
Indication for Procedure			0.91
Elective	137 (71.7)	143 (72.2)	
ACS	54 (28.3)	55 (27.8)	
Type of Procedure			0.013
Diagnostic	86 (45.0)	114 (57.6)	
Intervention	105 (55.0)	84 (42.4)	
Aspirin use	160 (83.8)	166 (83.8)	0.99
P2Y12 inhibitor use	146 (76.4)	146 (73.7)	0.54
Anticoagulation (NOAC/Warfarin)	25 (13.1)	23 (11.6)	0.66
Heparin dose	5,754 ± 2,161	5,990 ± 2,203	0.29
Sheath size			0.32
4 Fr	0 (0)	1 (0.5)	
5 Fr	11 (5.8)	5 (2.5)	
6 Fr	176 (92.6)	188 (95.4)	
7 Fr	2 (1.1)	3 (1.5)	
8 Fr	1 (0.5)	0 (0)	
Pulse oximetry used (BT)	186 (97.4)	190 (96.5)	1.60
<p>Values are mean ± SD or n (%).</p> <p>P-value from independent t-test for continuous variables and Pearson's chi-squared test (or Fisher's exact test where appropriate) for categorical variables.</p> <p>ACS, acute coronary syndrome; BT, Barbeau Test; NOACs, Novel Oral Anticoagulants</p>			

Table 3: Primary and secondary outcomes.

Variable	No Statseal (HC) n=191	With Statseal (AC) n=198	P value
Radial artery occlusion (RAO)	14 (6.3)	13 (4.1)	0.33
Re-bleeding	7 (3.7)	11 (5.6)	0.37
Haematoma	9 (4.7)	24 (12.1)	0.009
Compression time, mins	165.8 ± 63.1	79.7 ± 41.2	<0.001
<p><i>Values are mean ± SD or n (%).</i></p> <p><i>P-value from independent t-test for continuous variables and Pearson's chi-squared test (or Fisher's exact test where appropriate) for categorical variables.</i></p> <p>ACS, acute coronary syndrome; BT, Barbeau Test</p>			

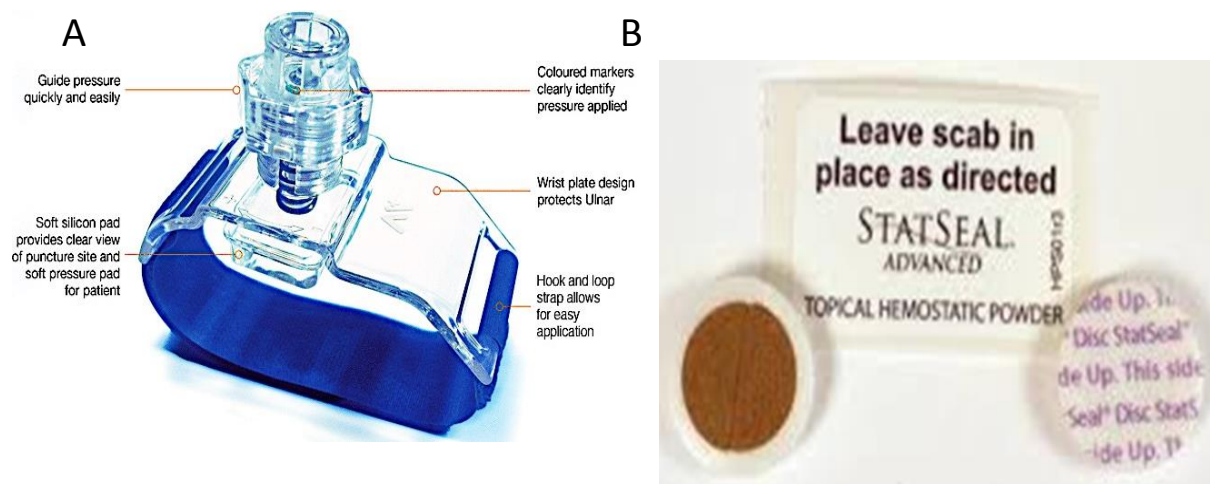


Figure 1: Study devices: (A) Helix™ compression device and (B) StatSeal™ Advance disc

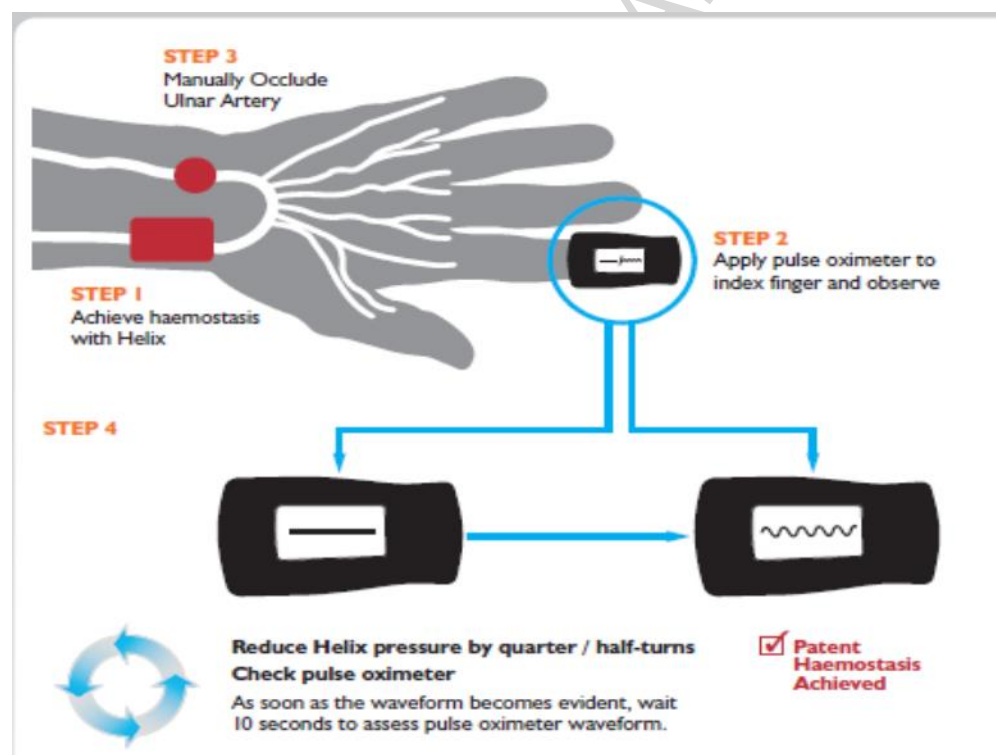


Figure 2: How to achieve patent haemostasis



Figure 3: Positioning of StatSeal™ Advanced Disc

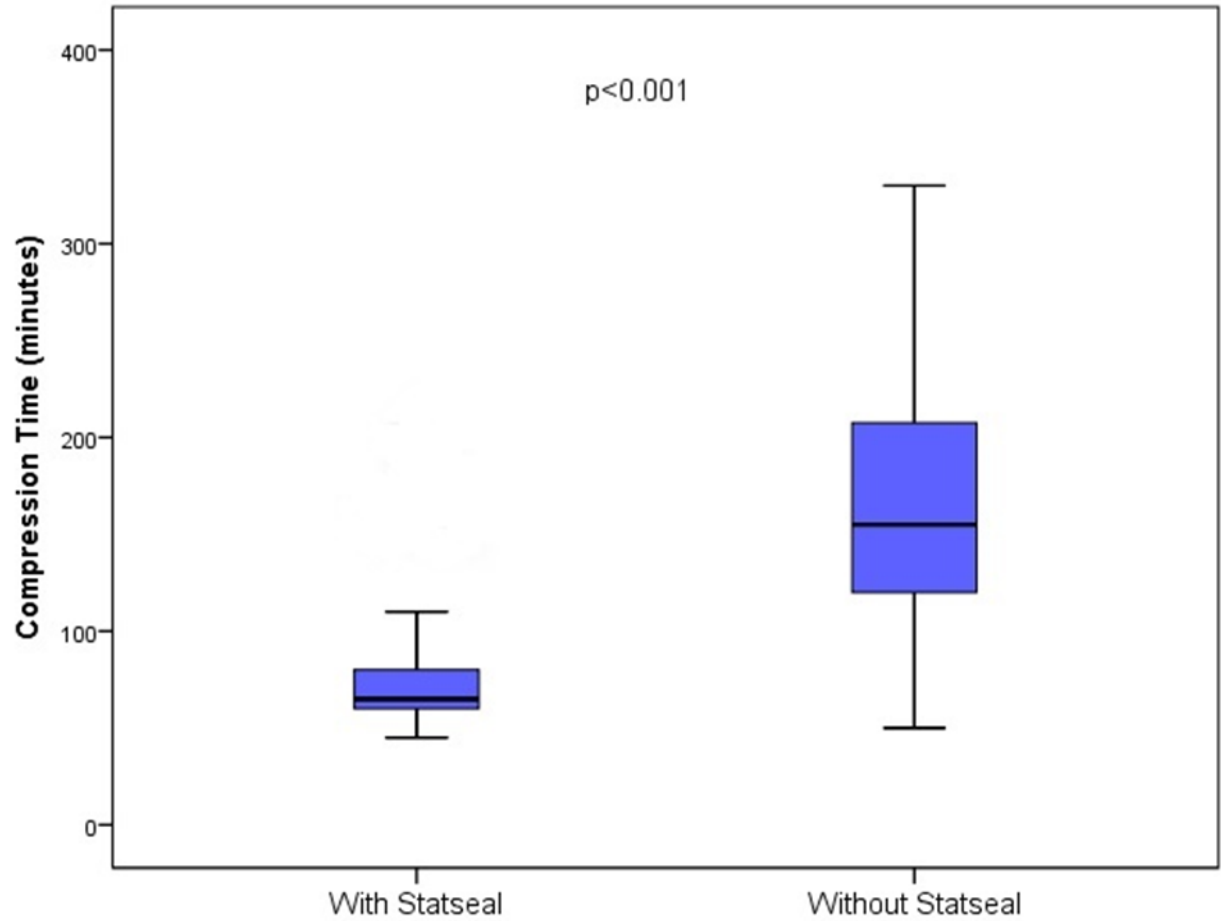


Figure 4: Time to haemostasis.

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Highlights

- Radial artery occlusion has been linked to flow reduction and prolonged compression. We aimed to investigate the effectiveness and safety of an accelerated band removal protocol, facilitated by a hemostasis promoting pad with patent haemostasis.
- Our randomized trial of 389 patients (191 patients received standard haemostatic compression and 198 received accelerated compression). The compression time was significantly reduced by more than 1/3 of the time, compared to standard compression (165.8 ± 63.1 versus 79.7 ± 41.2 minutes, $p < 0.001$).
- There were no significant differences in re-bleeding and RAO between groups (3.7% versus 5.6%, $p = 0.37$ and 6.3% versus 4.1%, $p = 0.33$) respectively. Incidence of haematoma was higher in accelerated compression group (4.7% versus 12.1%, $p = 0.009$).